

IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA

---

In re:  
BAXTER HEALTHCARE CORPORATION  
GAMMAGARD® PRODUCTS LIABILITY LITIGATION

---

This Document Relates to:  
ALL ACTIONS

---

MDL NO. 95-1060-R  
The Honorable Manuel L. Real

**NOTICE OF CLASS ACTION SETTLEMENT**

**TO: ALL PERSONS WHO RECEIVED GAMMAGARD® INTRAVENOUS IMMUNE GLOBULIN (IVIG) BETWEEN JANUARY 1, 1993 AND FEBRUARY 24, 1994 AND THEIR REPRESENTATIVES, ESTATES, AND SURVIVING SPOUSES, PARENTS, AND CHILDREN**

**PLEASE READ THIS NOTICE CAREFULLY.  
THIS CLASS ACTION SETTLEMENT AFFECTS YOUR IMPORTANT LEGAL RIGHTS.**

You are notified of:

- The conditional certification of a settlement class consisting of certain persons who received an infusion of Gammagard® IVIG and certain of their family members.
- The preliminary approval of a nationwide class action settlement under which Baxter Healthcare Corporation will pay benefits to qualified settlement class members.
- Your rights as a settlement class member to comment on or object to, participate in, or exclude yourself from the settlement.
- A court hearing on **September 18, 2000** to determine the fairness, adequacy, and reasonableness of the settlement.
- Important dates for all settlement class members:

<b>Deadline to Request Free HCV Test Kit .....</b>	<b>April 24, 2000</b>
<b>Deadline to Exclude Yourself or "Opt Out" of the Settlement .....</b>	<b>June 30, 2000</b>
<b>Deadline to File a Claim under the Settlement .....</b>	<b>June 30, 2000</b>

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

## CONTENTS

	<b>PAGE</b>
<b>I. THE GAMMAGARD® IVIG LITIGATION AND SETTLEMENT</b> .....	3
A. Background of the Litigation.....	3
B. Class Actions in General.....	3
C. The Settlement.....	3
D. Class Representatives .....	4
E. Class Counsel.....	4
<b>II. PERSONS WHO ARE SETTLEMENT CLASS MEMBERS</b> .....	4
<b>III. SUMMARY OF THE SETTLEMENT</b> .....	4
A. Overview of Settlement Benefits .....	5
B. Proof of Infusion .....	5
C. Free HCV Testing.....	5
D. Basic Payments .....	5
E. Additional Payments .....	7
F. Baxter's Rights and Obligations.....	7
G. Payment and Release.....	8
<b>IV. CLAIMS ADMINISTRATION</b> .....	8
A. Settlement Administrator.....	8
B. Filing of Claims and Applications .....	9
C. Maintenance of Records.....	9
<b>V. EXCLUSION FROM OR OPTING OUT OF THE SETTLEMENT</b> .....	9
<b>VI. SETTLEMENT APPROVAL HEARING ON September 18, 2000</b> .....	9
<b>VII. EFFECT OF FINAL APPROVAL; BAR ORDER</b> .....	10
<b>VIII. ATTORNEYS' FEES AND EXPENSES</b> .....	10
A. Class Counsel Fees and Expenses .....	10
B. Individual Counsel Fees and Expenses .....	10
C. No Contingent Fees for Basic Payments .....	11
<b>IX. EXAMINATION OF SETTLEMENT AGREEMENT AND OTHER DOCUMENTS</b> .....	11
<b>X. CONTACT CLASS COUNSEL</b> .....	11

**ATTACHMENT A-- DEFINITIONS OF QUALIFYING CONDITIONS**

**ATTACHMENT B-- CHALLENGE PROCEDURES**

**ATTACHMENT C -- GAMMAGARD® IVIG CLASS ACTION SETTLEMENT RELEASE**

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

## I. THE GAMMAGARD® IVIG LITIGATION AND SETTLEMENT

### A. Background of the Litigation

Baxter Healthcare Corporation processed an intravenous immune globulin (IVIG) called Gammagard®, which was an intravenous therapy prescribed by licensed medical doctors for patients with various immune system disorders. The medical conditions for which Gammagard® IVIG was commonly prescribed include, but are not limited to, the following:

- Primary Immune Deficiencies such as:
  - Congenital Agammaglobulinemias
  - Common Variable Immunodeficiency (CVID)
  - Wiskott-Aldrich Syndrome
  - Severe Combined Immunodeficiencies (SCID)
- B-Cell Chronic Lymphocytic Leukemia (CLL)
- Idiopathic Thrombocytopenic Purpura (ITP)

A number of individuals who used Gammagard® IVIG between January 1, 1993 and February 24, 1994 (the “Window Period”) claim to have become infected with the Hepatitis C Virus (“HCV”) from Gammagard® IVIG. If any HCV infection occurred, Baxter claims, it occurred as a result of changes in the source plasma mandated by the federal government. The number of patients receiving Gammagard® IVIG during the Window Period is not known but is estimated to be several thousand. Anyone who received Gammagard® IVIG during the Window Period may have been exposed to HCV.

Both class actions and numerous individual actions have been filed against Baxter Healthcare Corporation and Baxter International Inc. (collectively, “Baxter”) for negligence, strict liability, breach of implied and express warranty, fraud, misrepresentation, and infliction of emotional distress. These lawsuits allege, among other things, that individuals who were infused with Gammagard® IVIG during the Window Period were exposed to and/or infected with HCV. Baxter denies these allegations and has asserted various defenses.

**These lawsuits involve only Gammagard® IVIG used during the Window Period. They do not involve Gammagard® S/D IVIG, which is different than Gammagard® IVIG. Gammagard® S/D IVIG has not been the subject of claims nor is it included in the class action or this settlement.**

On June 9, 1995, all actions filed in federal court were transferred to the United States District Court for the Central District of California for coordinated proceedings before the Honorable Manuel L. Real (“the Court”). On March 1, 1996, the Court certified a nationwide class action, among other things. The plaintiffs undertook factual investigation, reviewed thousands of documents, took depositions, and consulted with experts. The parties litigated two appeals. After 14 months of negotiations under the supervision of the Court-appointed Special Master, the parties entered into a Settlement Agreement on October 15, 1999.

The plaintiffs and Baxter believe that the final outcome of the lawsuits, if they were to proceed through trial and appeals, is uncertain. While asserting that the claims have no merit, Baxter has nonetheless agreed to enter into a settlement as a compromise of disputed claims and to bring the litigation substantially to an end. Based upon their evaluation of the facts and law, the parties have determined that the proposed settlement is fair, reasonable and adequate. They have reached this conclusion based on the substantial benefits the settlement provides to settlement class members; the risks, uncertainties and costs of litigation; and the desirability of providing benefits to class members promptly rather than continuing protracted litigation.

The Court has preliminarily approved the settlement, under which monetary benefits will be paid to qualified settlement class members. The Court has made no final ruling as to the merits of the class allegations or Baxter’s denials and defenses. Distribution of this Notice is not a Court ruling or opinion as to the likelihood of recovery by the class or as to the merits of Baxter’s defenses. The purpose of this Notice is only to inform settlement class members about the proposed settlement and their rights under the settlement.

### B. Class Actions In General

A class action is a lawsuit in which the claims and rights of a group of people are decided in a single court proceeding brought by representative plaintiffs (the “class representatives”), without the necessity of each person filing his or her own lawsuit or appearing as an individual plaintiff. Class actions are used when there are common issues of law or fact raised by all claims. Use of the class action eliminates the cost, waste, and delay of multiple lawsuits and ensures that all class members are treated similarly. The Court has a responsibility to assure that resolution of the class claims is fair.

### C. The Settlement

The purpose of the settlement is to identify those individuals who may be infected with HCV through the use of Gammagard® IVIG during the Window Period. The settlement recognizes that such individuals fall into three subclasses:

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

(1) **Current Infection.** Those Gammagard® IVIG Recipients who are currently infected with HCV as a result of their infusion with Gammagard® IVIG and who therefore face the risk of future complications arising from those infections;

(2) **Past Infection.** Those Gammagard® IVIG Recipients who were previously infected with HCV as a result of their infusion with Gammagard® IVIG but who no longer face the risk of future complications, either because they have “cleared” the virus or because they are no longer alive; and

(3) **Exposure Only.** Those Gammagard® IVIG Recipients who were previously exposed to possible HCV infection as a result of their infusion with Gammagard® IVIG but who currently do not appear to have experienced a resulting HCV infection.

#### **D. Class Representatives**

Three people, who are called the “class representatives,” have agreed to litigate their claims on behalf of themselves and all settlement class members. The class representatives are Kristen Renee Geary (Current Infection), John Mavrikos (Past Infection), and Brenda Johnson (Exposure Only). The Court has determined that the class representatives’ claims are typical of the claims of all settlement class members within each category and that these representatives will fairly and adequately protect and pursue the interests of the class members.

#### **E. Class Counsel**

The Court has also appointed certain attorneys who are qualified, experienced, and able to conduct this litigation and represent all settlement class members (“Class Counsel”). A list of Class Counsel, indicating which subclass of settlement class members each represents, is provided on page 11 of this Notice. **Settlement class members are not individually responsible for the costs or fees of Class Counsel. Settlement class members may, but are not required to, retain individual counsel.**

## **II. PERSONS WHO ARE SETTLEMENT CLASS MEMBERS**

On December 20, 1999, the Court conditionally certified a settlement class consisting of certain persons who received an infusion of Gammagard® IVIG during the Window Period and certain of their family members. Settlement class members are:

1. All citizens or permanent residents of the United States who received an infusion of Gammagard® IVIG during the Window Period (referred to as “Recipients”); OR
2. The estate of any deceased Recipient; OR
3. In the absence of an estate, a surviving spouse of any deceased Recipient; OR
4. In the absence of an estate or a surviving spouse, the surviving children of any deceased Recipient; OR
5. In the absence of an estate, a surviving spouse or surviving children, the parents of any deceased Recipient.

Specifically **EXCLUDED** as settlement class members are:

1. Any person whose claim is based upon a Recipient who was the subject of a previously settled claim or lawsuit against Baxter relating to alleged exposure to, and/or infection with, HCV arising from the use of Gammagard® IVIG; OR
2. Any person whose claim is based upon or related to a Recipient who was the subject of a lawsuit against Baxter involving the alleged exposure to, and/or infection with, HCV arising from the use of Gammagard® IVIG that has proceeded to final judgment or been dismissed with prejudice.

A person who is covered by the above class definition is a settlement class member, regardless of whether or not such person has a pending lawsuit regarding Gammagard® IVIG in state or federal court, and whether or not such person presently is infected with HCV.

All potential settlement class members are encouraged to contact healthcare providers promptly and consult medical records to determine if they or their deceased spouse, parent, or child received Gammagard® IVIG during the Window Period. **IMPORTANT: A settlement class member who does not timely and properly file a claim is not entitled to share in the settlement. A settlement class member who neither files a claim nor excludes him/herself from the settlement shall be forever barred from seeking any damages or other payments from Baxter arising out of alleged exposure to, and/or infection with, HCV resulting from the use of Gammagard® IVIG during the Window Period.**

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

### III. SUMMARY OF THE SETTLEMENT

The Settlement Agreement, entitled "Class Action Settlement Agreement Re Gammagard® Intravenous Immune Globulin Claims," was filed with the Court on **December 20, 1999**. The following is only a summary of the settlement and is qualified entirely by the Settlement Agreement, which can be examined as described below under the heading "Examination of Settlement Agreement and Other Documents."

#### A. Overview of Settlement Benefits

There are two basic types of payments that settlement class members may be eligible to receive. Class members who can establish infusion with Gammagard® IVIG during the Window Period may apply for "Basic Payments" as described below. In addition, some class members who can establish both their right to a "Basic Payment" and satisfy medical criteria establishing that the Recipient's HCV infection caused progression to certain serious medical conditions or death may apply for "Additional Payments" also described below.

The settlement also provides that settlement class members can elect to have their blood tested at Baxter's expense to determine whether they are currently infected with HCV. Alternatively, a class member can choose to have a blood test done at a facility of his/her choice.

Settlement class members have a choice. They can elect to seek benefits under this settlement by filing a claim and other necessary documents as described below OR they can choose not to participate in the settlement and "opt out" by filing a simple written request. If a class member opts out, he/she retains whatever rights he/she currently has to proceed with a claim against Baxter relating to alleged exposure or infection with HCV arising out of the use of Gammagard® IVIG during the Window Period.

#### B. Proof of Infusion

All settlement class members who request free HCV testing and/or submit Claims must demonstrate that the Recipient was infused with Gammagard® IVIG during the Window Period. "Proof of Infusion" is established by presenting one of the following:

(1) Medical records indicating that the Recipient received one or more infusions of Gammagard® IVIG during the Window Period, together with a letter or some other proof that the medical records are accurate copies of records from a physician, clinic, hospital, or other medical care provider; OR

(2) Medical records indicating that a treating physician prescribed Gammagard® IVIG by name for infusion for the Recipient during the Window Period and that the Recipient received one or more infusions of an intravenous immune globulin during the Window Period, together with a letter or some other proof that the medical records are accurate copies of records from a physician, clinic, hospital, or other medical care provider; OR

(3) Pharmacy records indicating that the Recipient received one or more infusions of Gammagard® IVIG during the Window Period, together with a letter or some other proof that the medical records are accurate copies of records from a physician, clinic, hospital, or other medical care provider; OR

(4) A treating physician's verified statement that the treating physician prescribed Gammagard® IVIG for the Recipient and that the Recipient received one or more infusions of an intravenous immune globulin during the Window Period or that the treating physician has direct knowledge that the Recipient received one or more infusions of Gammagard® IVIG during the Window Period.

#### C. Free HCV Testing

A blood test called a Polymerase Chain Reaction, commonly referred to as a "PCR Test," can detect HCV even if you have no symptoms. To qualify for certain settlement benefits, a settlement class member must submit a positive PCR Test. Class members can provide a PCR Test result or, if he/she can demonstrate Proof of Infusion, may request a free HCV Test Kit to be paid for by Baxter. The class member can take the HCV Test Kit to his or her doctor to have a blood sample drawn and the doctor will send the blood sample to a lab for PCR testing. When the class member's doctor receives the test results, the class member can assess his/her personal medical condition and decide whether to participate in or to exclude him/herself from the settlement.

The instructions for requesting a HCV Test Kit are detailed in the "Instructions for Participating in the Gammagard® IVIG Class Action Settlement," a copy of which is enclosed in the Information Packet. **The deadline for submitting a request for a Test Kit is April 24, 2000.**

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

#### D. Basic Payments

Settlement class members may submit Claims for one of the following three Basic Payments:

(1) **Exposure Only Payment.** Exposure Only Payments involve those Recipients who do not claim prior or current HCV infection. When a settlement class member submits a properly completed Claim which demonstrates Proof of Infusion by the Recipient but does not demonstrate that the Recipient became infected with HCV as a result of such infusion, the settlement class member shall be entitled to an Exposure Only Payment of \$1500, provided that the Claim is either unchallenged by Baxter or approved after challenge. In no event, however, shall more than one \$1500 payment be made in connection with the same Recipient. If two or more settlement class members submit qualified Claims in connection with the same deceased Recipient, the \$1500 payment shall be divided equally among the qualified Claims.

The instructions for submitting a proper Claim for an Exposure Only Payment are detailed in the enclosed "Instructions for Participating in the Gammagard® IVIG Class Action Settlement."

**The deadline for submitting a Claim Form for an Exposure Only Payment is June 30, 2000**

(2) **Past Infection Payment.** Past Infection Payments involve those Recipients who were previously infected with HCV but who either "cleared" the virus or were deceased as of October 15, 1999. When a settlement class member submits a properly completed Claim which demonstrates Proof of Infusion by the Recipient and infection with HCV as a result of such infusion, but fails to show that the Recipient was still living with that infection as of October 15, 1999 (either because the Recipient cleared the virus subsequent to the infection, or because the Recipient was no longer alive as of October 15, 1999), the settlement class member shall receive one of the following Past Infection Payments, provided that the Claim is either unchallenged by Baxter or approved after challenge:

(a) If the Claim establishes that the Recipient either cleared the virus (as determined by the date of the first negative PCR Test following the last positive PCR Test) or died during the period of time from January 1, 1993 through December 31, 1994, the Past Infection Payment shall be \$70,000.

(b) If the Claim establishes that the Recipient either cleared the virus or died during the period of time from January 1, 1995 through December 31, 1996, the Past Infection Payment shall be \$80,000.

(c) If the Claim establishes that the Recipient either cleared the virus or died during the period of time from January 1, 1997 through October 15, 1999, the Past Infection Payment shall be \$90,000.

In no event, however, shall more than one Past Infection Payment be made in connection with the same Recipient. If two or more settlement class members file qualified Claims in connection with the same deceased Recipient, the Past Infection Payment shall be divided equally among the qualified Claims.

The instructions for submitting a proper Claim for a Past Infection Payment are detailed in the enclosed "Instructions for Participating in the Gammagard® IVIG Class Action Settlement."

**The deadline for submitting a Claim Form for a Past Infection Payment is June 30, 2000.**

(3) **Current Infection Payment.** Current Infection Payments involve Recipients who can prove HCV infection as of October 15, 1999. When a settlement class member submits a properly completed Claim which demonstrates Proof of Infusion by the Recipient, the Recipient was infected with HCV as a result of such infusion, and the Recipient was living with that HCV infection as of October 15, 1999, the settlement class member shall receive a Current Infection Payment, provided that the Claim is either unchallenged by Baxter or approved after challenge. The amount of the Current Infection Payment shall depend upon the age of the Recipient on February 1, 1998, as follows:

<u>Age of Recipient on 2-1-98</u>	<u>Payment</u>
Under 21 years of age	\$150,000
21 – 40 years of age	\$140,000
41 – 60 years of age	\$130,000
Over 61 years of age	\$100,000

Further, if within five years of October 15, 1999, a Recipient who has previously received a Past Infection Payment has a subsequent positive PCR Test, such Recipient may apply to the Court for a determination that such infection was caused by the Recipient's infusion with Gammagard® IVIG during the Window Period. If such application is sustained by the Court, Baxter shall pay the Recipient the difference between the Past Infection Payment and the Current Infection Payment that the Recipient would have received had such continuing infection been known as of the date of the Past Infection Payment.

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

The instructions for submitting a proper Claim for a Current Infection Payment are detailed in the enclosed "Instructions for Participating in the Gammagard® IVIG Class Action Settlement." **The deadline for submitting a Claim Form for a Current Infection Payment is June 30, 2000.**

## **E. Additional Payments**

Any settlement class member who qualifies for a Past Infection Payment or a Current Infection Payment may also apply for one or more of the Additional Payments specified below in connection with certain medical conditions arising out of the Recipient's HCV infection. If the settlement class member received a Current Infection Payment prior to submitting an application for an Additional Payment, the settlement class member must demonstrate the Recipient's continuing HCV infection since the date of the Current Infection Payment. The instructions for submitting an application for an Additional Payment are detailed in the enclosed "Instructions for Participating in the Gammagard® IVIG Class Action Settlement." **There is no deadline for submitting an application for an Additional Payment.**

(1) **Additional Payment for Qualifying Conditions.** The Qualifying Conditions are Ascites, Cryoglobulinemia, Esophageal Variceal Hemorrhage, Hepatocellular Carcinoma, Portal Systemic Encephalopathy, Renal Failure, and Spontaneous Bacterial Peritonitis. The definitions of these Qualifying Conditions are in Attachment "A" attached to this Notice.

A settlement class member who receives either a Past Infection Payment or a Current Infection Payment shall be eligible to receive an Additional Payment of \$225,000 if the subject Recipient has been or is subsequently diagnosed with one or more Qualifying Conditions and HCV is the "Primary Cause" of the Qualifying Condition(s). HCV is the "Primary Cause" of the Qualifying Condition if the Qualifying Condition was caused by HCV more than any other single cause. If the diagnosis is made subsequent to **December 22, 1999** the Additional Payment shall be increased by two and one-half percent (2.5%) per year, compounded annually, beginning one year after **December 22, 1999**, for a period of time up to a maximum of 30 years after **December 22, 1999** and ending in the year that the Recipient is first diagnosed with any one or more of the Qualifying Conditions. This payment for Qualifying Conditions shall be a one-time payment upon first demonstration of eligibility and the settlement class member shall not be entitled thereafter to any Additional Payments for Qualifying Conditions even if the Recipient develops additional Qualifying Conditions. In no event shall more than one Additional Payment for Qualifying Conditions be made in connection with the same Recipient. If two or more settlement class members file qualified applications in connection with the same Recipient, the Additional Payment for Qualifying Conditions shall be divided among the qualified applications.

(2) **Additional Payment for First and Second Liver Transplants.** A Liver Transplant is an operation in which all functions of the liver necessary for survival are substituted by another organ (homograft or xenograft) with the intent of permanent implantation and function. A settlement class member who receives either a Past Infection Payment or a Current Infection Payment shall be eligible to receive an Additional Payment of \$225,000 if the subject Recipient has undergone a Liver Transplant with respect to which the Recipient's HCV Infection or Qualifying Condition is the "Primary Cause." HCV or the Qualifying Condition is the "Primary Cause" of the Liver Transplant if the Liver Transplant was made necessary by HCV or the Qualifying Condition more than any other single cause. If the Liver Transplant takes place subsequent to the **December 22, 1999**, the Additional Payment shall be increased by two and one-half percent (2.5%) per year, compounded annually, beginning one year after **December 22, 1999**, for a period of time up to a maximum of 30 years after **December 22, 1999**.

In the event that the Recipient undergoes a second Liver Transplant made necessary due to HCV Infection, any Qualifying Condition, or the failure of the first Liver Transplant as the "Primary Cause," the settlement class member shall be eligible to receive a further payment of \$125,000. If the Liver Transplant takes place subsequent to **December 22, 1999**, the Additional Payment shall be increased by two and one-half percent (2.5%) per year, compounded annually, beginning one year after **December 22, 1999** for a period of time up to a maximum of 30 years after **December 22, 1999**. No settlement class member shall be entitled to any further payments for Liver Transplant even if the subject Recipient undergoes more than two Liver Transplants. If two or more settlement class members file qualified applications in connection with the same Recipient, the Additional Payment for Liver Transplant shall be divided among the qualified applications.

(3) **Additional Payment for Death.** A settlement class member who receives either a Past Infection Payment or a Current Infection Payment shall be eligible to receive an Additional Payment of \$250,000 if the subject Recipient has died, or subsequently dies, due to HCV infection, any Qualifying Condition, or the failure of a Liver Transplant as the "Primary Cause." HCV, the Qualifying Condition, or failure of the Liver Transplant is the "Primary Cause" of death if the death was caused by HCV, the Qualifying Condition, or failure of a Liver Transplant more than by any other single cause. If such death takes place subsequent to **December 22, 1999**, the Additional Payment shall be increased by two and one-half percent (2.5%) per year, compounded annually, beginning one year after **December 22, 1999** for a period of time up to a maximum of 30 years after **December 22, 1999**. If two or more settlement class members file qualified applications in connection with the same Recipient, the Additional Payment for Death shall be divided among the qualified applications.

## **F. Baxter's Rights and Obligations**

(1) **Baxter's Financial Obligations.** Baxter is responsible for the reasonable costs of this Notice, administering the

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

settlement program, court-approved attorneys' fees, and approved settlement payments. Baxter has already made deposits into a Settlement Fund for these purposes, and shall make additional future deposits as the Court and Settlement Administrator deem necessary.

(2) **Baxter's Right of Withdrawal.** After the deadline for opting out and filing Claims for Basic Payments, Baxter will decide whether it wishes to confirm its participation in this settlement or, alternatively, withdraw from this settlement. If Baxter chooses to withdraw, notice will be sent to all settlement class members known to the Settlement Administrator. In such event, no payments will be made to settlement class members and all class members will be in the same position as if the settlement had never occurred.

(3) **Baxter's Right to Challenge Claims for Basic Payments.** Generally, Baxter has the right to review all Claims for compliance with the requirements for Basic Payments and to challenge Claims which are deemed inadequate. In addition, if Baxter challenges a Claim for a Past Infection Payment or a Current Infection Payment, Baxter may submit a request for additional information to the class member. The Court-appointed Special Master will review all challenges, and may request additional information from either party. The settlement class member will have the opportunity to respond and/or object to such challenges and/or information requests. The Special Master will issue a written decision, which may be reviewed by the Court. Detailed instructions for the challenge process are in Attachment "B" attached to this Notice.

(4) **Baxter's Right to Challenge Applications for Additional Payments.** If Baxter deems an application for an Additional Payment inadequate, Baxter may: (1) request additional medical documentation or responses to written questions; (2) submit the application form and medical records to a physician; (3) conduct an interview of the Recipient and/or settlement class member; and/or (4) require the Recipient to submit to a new medical examination. Generally, Baxter also has the right to challenge applications which are deemed inadequate. The settlement class member will have the opportunity to respond and/or object to such challenges. The challenge will be decided by a three-person panel of health care professionals. The decision of the panel may be entered as a judgement of the court, and may be challenged solely on the grounds specified in Sections 10 and 11 of the Federal Arbitration Act (9 U.S.C. §§10-11). The fees and costs of the panel will be paid by Baxter, unless the panel denies the application and also finds that the application was either frivolous or presented without a good faith belief that the Recipient qualified for the Additional Payment (in which case, the settlement class member shall pay the fees and costs of the panel). Notwithstanding the foregoing, each party is responsible for his or her own attorney's fees and costs. Detailed instructions for the challenge process are in Attachment "B" attached to this Notice.

#### **G. Payment and Release**

(1) **Basic Payments.** If a Claim is approved for payment, the Settlement Administrator will make the Basic Payment to the settlement class member; provided, however, that any class member entitled to either a Past Infection or Current Infection Payment must first properly execute a Release in the form in Attachment "C" attached to this Notice. Any settlement class member who submits an unsuccessful Claim for either a Past Infection Payment or a Current Infection Payment shall nonetheless receive an Exposure Only Payment if it is determined that the Recipient was infused with Gammagard® IVIG during the Window Period.

(2) **Additional Payments.** If Baxter does not challenge the application for an Additional Payment, payment will be made by Baxter. If Baxter brings a challenge, and the panel ultimately decides in favor of the settlement class member, the Additional Payment will be made within 30 days of the decision. Such payment will include interest at the rate of 6% per annum simple interest from 150 days after the submission of the application for Additional Payment.

### **IV. CLAIMS ADMINISTRATION**

#### **A. Settlement Administrator**

After consulting with the parties, the Court has appointed Navigant, Inc. as the Settlement Administrator. The Settlement Administrator will, with the assistance of claim officers and employees, be responsible for processing and evaluating claims. The Settlement Administrator is not permitted to give legal advice. The Settlement Administrator will be subject to the continuing jurisdiction of the Court and subject to Court review. Baxter will be responsible for the Settlement Administrator's costs.

If you elect to participate in the settlement, your principal contact will be the Settlement Administrator. All forms and supporting documents will be submitted to the Settlement Administrator for initial processing. The Settlement Administrator can be contacted by:

- (1) Writing:  
Settlement Administrator  
Gammagard® IVIG Settlement  
P.O. Box 131620  
Dallas, TX 75313

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

(2) Calling Toll Free: 1-888-921-4776.

In addition, the Settlement Agreement, Forms, and settlement updates will be posted to the settlement class internet site (<http://www.hcv-claims.com>).

Please do not contact the Court. The Court is not equipped to answer your questions concerning the settlement or individual settlement claims.

#### **B. Filing of Claims and Applications**

The deadline for exclusion from (opting out of) the settlement is **June 30, 2000**. The deadline for filing Claim Forms for Basic Payments is also **June 30, 2000**. Applications for Additional Payments may be filed at the same time as Claims for Basic Payments, but there is no deadline. Only the Forms enclosed in the Information Packet may be used to submit Claims for Basic Payments and applications for Additional Payments. Additional copies may be obtained from the Settlement Administrator or the settlement class internet site (<http://www.hcv-claims.com>). The instructions and requirements for filing Claims and applications are detailed in the enclosed "Instructions for Participating in the Gammagard® IVIG Class Action Settlement." It is important to read these instructions carefully, and to begin preparing the Forms as soon as possible, to ensure that the Forms and documents are filed correctly and timely.

#### **C. Maintenance of Records**

The Settlement Administrator shall sign a confidentiality statement with respect to all information concerning settlement class members, subject to Class Counsel's and Baxter's rights to review and/or obtain such information.

After all Claims for Basic Payments and related applications for attorneys' fees are resolved and paid, the Settlement Administrator shall close all administrative facilities, preserving for future availability all documents and records that may be relevant to potential applications for Additional Payments. After the Settlement Administrator is closed, Baxter will continue to receive and process all applications for Additional Payments.

#### **V. EXCLUSION FROM OR OPTING OUT OF THE SETTLEMENT**

Participation in this settlement is optional, not mandatory. If a settlement class member wants to exclude him/herself from or opt out of the settlement class, he/she must submit a written and signed request for exclusion, **postmarked on or prior to June 30, 2000** to:

Settlement Administrator  
Gammagard® IVIG Settlement  
P.O. Box 131620  
Dallas, TX 75313

The request for exclusion must be signed by (1) the settlement class member, except that a parent or legal guardian must sign for a settlement class member who is a minor or who is not otherwise legally competent to contract, and (2), if any, the settlement class member's attorney. If a timely request for exclusion and a timely Claim are submitted by or relating to the same Recipient, the Settlement Administrator shall attempt to contact the settlement class member(s) who filed the conflicting documents to determine if one of the documents will be withdrawn. In the absence of such withdrawal, the Claim shall be disregarded by the Settlement Administrator.

Any person who submits a timely request for exclusion shall not be barred by the final judgment entered in this litigation and shall retain whatever rights that person may have to proceed with claims against Baxter relating to alleged exposure to, and/or infection with, HCV arising out of the use of Gammagard® IVIG. The statute of limitations applicable to such claims shall be tolled from November 22, 1994, until the date of the request for exclusion.

#### **VI. SETTLEMENT APPROVAL HEARING ON SEPTEMBER 18, 2000**

The Court will hold a hearing on **September 18, 2000 at 10 a.m.** at the United States District Court for the Central District of California, **Courtroom of the Honorable Manuel Real**, 312 North Spring Street, Los Angeles, California 90012, to determine whether the proposed settlement is fair, reasonable, adequate, and in the best interests of the class. The Settlement Approval Hearing may be adjourned from time to time by the Court without further notice. Notice of any such adjournment may only be provided by announcement at the hearing. At the hearing, any settlement class member may appear in person or by counsel and be heard to the extent allowed by the Court in support of, or in opposition to, the fairness, reasonableness, and adequacy of the settlement or any of the other matters to be considered by the Court; provided, however, that in no event will a person be heard unless, on or before **June 30, 2000** (hand delivered or postmarked), such person files with the Clerk of the Court, United States District Court for the Central District of California, 312 North Spring Street, Los Angeles, California 90012, the following documents:

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

- (a) notice of such person's intention to appear;
- (b) a detailed statement that describes the specific grounds to be raised; and
- (c) any supporting documentation that such person desires the Court to consider, including any memorandum or brief.

DO NOT CALL THE COURT. ALL REQUESTS MUST BE IN WRITING.

At the same time, copies of such documents shall be served in person or by mail upon each of the following attorneys:

Class Counsel

John C. Evans, Esq.  
SPECTER SPECTER EVANS &  
MANOQUE, P.C.  
The 26th Floor  
Koppers Building  
Pittsburgh, PA 15219

Baxter Counsel

Baxter Healthcare Corporation  
Attn: General Counsel – Re: Gammagard® IVIG  
One Baxter Parkway  
Deerfield, IL 60015

Any person who fails to object in the manner provided herein shall be deemed to have waived his/her objections and shall be forever barred from making any such objections in this litigation.

**VII. EFFECT OF FINAL APPROVAL; BAR ORDER**

If the Court grants final certification of the settlement class and final approval of the Settlement Agreement, a final judgment pursuant to Federal Rule of Civil Procedure 54(b) shall be entered forever barring every settlement class member (other than persons who have or are deemed to have excluded themselves from or opted out of the settlement), from prosecuting any past, present or future, known or unknown claim or lawsuit against Baxter relating to alleged exposure to, and/or infection with, HCV arising out of the infusion, administration, receipt, or use of or contact with Gammagard® IVIG within the Window Period. The terms of such final judgment have the same effect as if such persons had executed appropriate releases.

The bar and release in favor of Baxter extends to all of its past, present, and future corporate parents, subsidiaries, divisions, affiliates, assigns, partners, and joint ventures, as well as all suppliers, distributors, pharmacies, medical providers, and other persons or entities, and also including all shareholders, directors, officers, employees, agents, servants, persons, insurers, reinsurers, and counsel for each of the foregoing as well as their predecessors and successors. This bar and release extends to parties other than Baxter, including claims which a settlement class member may have against a doctor or other medical provider.

**VIII. ATTORNEYS' FEES AND EXPENSES**

**A. Class Counsel Fees and Expenses**

At the Settlement Approval Hearing, Class Counsel will ask the Court for an award of attorneys' fees not to exceed \$18,000,000.00 and for reimbursement of expenses not to exceed \$3,000,000.00, to be paid by Baxter. Baxter has not agreed to a particular amount, but has agreed that it will pay Class Counsel fees and expenses as ordered by the Court. The payment of attorneys' fees and expenses to Class Counsel will not reduce any payment to settlement class members. **Settlement class members will NOT be individually responsible for Class Counsel's attorneys' fees and expenses. However, each class member is individually responsible for any legal fees and expenses for an individual attorney-client relationship, subject to the exceptions in the following section.**

**B. Individual Counsel Fees and Expenses**

(1) **Basic Payments.** If a settlement class member retains an attorney in connection with the submission of a Claim for either a Past Infection Payment or a Current Infection Payment or in connection with any challenge by Baxter, such attorney may submit an application for reasonable fees and costs to be paid from the Settlement Fund upon approval by the Special Master. Such applications may be made regardless of whether a challenge by Baxter is ultimately allowed or rejected; provided, however, that the reasonableness of the positions asserted by such attorney in connection with the Claim shall be considered when evaluating the application. Consistent with the foregoing, the Special Master may award attorneys' fees and costs under such terms and conditions as the Special Master deems fair and just, and that decision is reviewable by the Court.

(2) **Additional Payments.** An attorney who assists a settlement class member in connection with the submission of an application for an Additional Payment may not seek attorneys' fees and costs to be paid from the Settlement Fund for such assistance,

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

unless such application for Additional Payment is made at or before the time of the submission of the Supplemental Medical Information Form required in connection with the class member's Claim for a Basic Payment. In the latter situation, the attorney may submit the request for attorneys' fees and costs to the Special Master. The Special Master may award reasonable attorneys' fees and costs under such terms and conditions as the Special Master deems fair and just, and that decision is reviewable by the Court.

**C. No Contingent Fees for Basic Payments**

No attorney shall be entitled to any contingent share of any Basic Payment.

**IX. EXAMINATION OF SETTLEMENT AGREEMENT AND OTHER DOCUMENTS**

This Notice does not purport to be a complete description of the litigation, the Settlement Agreement, or the terms of the settlement. For a more detailed statement of the matters involved in the litigation, reference is made to the pleadings, to the Settlement Agreement, to the orders entered by the Court, and to the other papers filed in the litigation, which may be inspected at the Office of the Clerk of the Court, United States District Court for the Central District of California, 312 North Spring Street, Los Angeles, California 90012, during business hours of each business day. Please note that the Clerk's Office is not permitted to give legal advice. The Settlement Agreement also may be obtained from the Settlement Administrator or viewed on the settlement class internet site (<http://www.hcv-claims.com>).

**X. CONTACT CLASS COUNSEL**

Class Counsel are available to answer questions and provide information at no cost to settlement class members. Class Counsel may be contacted at:

John C. Evans, Esq.  
David J. Manogue, Esq.  
SPECTER SPECTER EVANS & MANOGUE, P.C.  
The 26th Floor - Koppers Building  
Pittsburgh, PA 15219  
(412) 642-2300  
**(Lead Class Counsel)**

**Counsel Representing Current Infection Claimants**

John C. Evans, Esq.  
SPECTER SPECTER EVANS & MANOGUE, P.C.  
The 26th Floor  
Koppers Building  
Pittsburgh, PA 15219  
(412) 642-2300

Arthur Sherman, Esq.  
SHERMAN SALKOW PETOYAN & WEBER, P.C.  
9454 Wilshire Boulevard  
Suite 550  
Beverly Hills, CA 90212  
(310) 275-5077

Donna Miller Rostant, Esq.  
HALL & SICKELS, P.C.  
12120 Sunset Hills Road  
Suite 150  
Reston, VA 20190  
(703) 925-0500

**Counsel Representing Past Infection Claimants**

Charles H. Johnson, Esq.  
CHARLES H. JOHNSON & ASSOCIATES, P.A.  
2599 Mississippi Street  
New Brighton, MN 55112  
(651) 633-5685

Arnold Levin, Esq.  
LEVIN FISHBEIN SEDRAN & BERMAN  
510 Walnut Street  
Suite 500  
Philadelphia, PA 19105  
(215) 592-1500

Wayne R. Spivey, Esq.  
David S. Shrager, Esq.  
SHRAGER MCDAID LOFTUS FLUM & SPIVEY  
Two Commerce Square  
2001 Market Street  
Philadelphia, PA 19103  
(215) 568-7771

**Counsel Representing Exposure Only Claimants**

Robert C. Huntley, Jr., Esq.  
HUNTLEY PARK THOMAS BURKETT  
OLSEN & WILLIAMS, LLP  
250 So. 5th Street  
Suite 660  
P. O. Box 2188  
Boise, ID 83701  
(208) 345-7800

Diane M. Nast, Esq.  
RODA & NAST  
801 Estelle Drive  
Lancaster, PA 17601  
(717) 892-3000

**You should save this Notice for Future Reference  
THIS NOTICE HAS BEEN APPROVED BY THE COURT**

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

## ATTACHMENT A

### DEFINITIONS OF QUALIFYING CONDITIONS

Settlement class members should note that the following medical terms necessarily involve technical words. You should consult your doctor about these medical conditions.

(A) **Ascites.** Ascites is an abdominal fluid collection within the peritoneal cavity. Proof of this condition shall require all of the following:

- (i) an abdominal ultrasound or computerized tomography ("CT") scan of the abdomen to confirm that ascitic fluid is present;
- (ii) an abdominal paracentesis that removes at least 500 milliliters of ascitic fluid; and
- (iii) paracentesis fluid analysis with all of the following tests and all of the following results:

TEST	RESULT
Cytology	Negative for malignancy
Polymorphonuclear (PMN) cell count	PMN <250/mm <sup>3</sup>
Serum -ascites albumin gradient (SAAG) (defined as ascites albumin subtracted from serum albumin)	SAAG>1.1
Protein	Ascites protein<3gm%
Bacterial culture at bedside in blood culture bottles, aerobic and anaerobic	No growth
Mycobacterial culture	No growth
Amylase	Ascites amylase less than serum amylase

The following conditions are possible "Alternative Causes" of Ascites in a patient with or without HCV: malignancy, primary or metastatic; protein-losing enteropathy; heart failure; ruptured viscus; tuberculosis; dengue, cholera or schistosomiasis; pancreatitis; kidney failure; chlamydia infection; fungal or parasitic infection in the peritoneum; peritonitis (other than spontaneous bacterial peritonitis); Budd Chiari syndrome; portal vein thrombosis or occlusion (intra or extra luminal); use of amiodarone; exposure to or ingestion of hepatotoxin; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

(B) **Cryoglobulinemia.** **Cryoglobulinemia** is an excess of certain immunoglobulins in the Recipient's serum. Proof of this condition shall require a test showing serum containing excess immunoglobulins which are insoluble in serum at temperatures between 10° and 37° C and one or more of the following clinical conditions:

- (i) renal failure;
- (ii) recurring necrotizing skin ulcers;
- (iii) infarction of a distal segment of one or more digits; or
- (iv) vasculitic lesions as evidence by purpura, arthritis or neuropathy.

The following conditions are possible "Alternative Causes" of Cryoglobulinemia in a patient with or without HCV: concomitant diagnosis of multiple myeloma or Waldenstrom's macroglobulinemia; cutaneous ulcers due to peripheral vasospastic disease, malignancy, hemoglobinopathy, necrobiosis lipoidica, pyoderma gangrenosum, Behcet's syndrome, erythema multiforme; history of traumatic occlusion of a digital artery in the digit exhibiting infarction; other causes of arthritis, neuropathy or vasculitic lesions; exposure to or ingestion of hepatotoxins; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

(C) **Esophageal Variceal Hemorrhage.** **Esophageal Variceal Hemorrhage** ("EVH") is an upper gastrointestinal hemorrhage from dilated veins in the esophagus. Proof of this condition shall require either:

- (i) The presence of active bleeding from an esophageal varix at the time of upper intestinal endoscopy ("UIE"); or
- (ii) Evidence of hemorrhage manifested by hemetesis, melanemesis, obvious blood in the stool, a heme positive aspirate of gastric contents after insertion of a nasogastric tube which initially returns bloody or coffee ground appearing material, or a significant blood loss from the upper gastrointestinal requiring transfusion with four or more units of packed red blood cells, subsequently confirmed by UIE within 72 hours of the manifestation that verifies the presence of stigmata of recent variceal hemorrhage (defined as the presence of a fresh, adherent blood clot or an acute white fibrin plug on the surface of a large and tortuous or coiled esophageal varix) and that verifies that bleeding was highly likely to have been from that source.

The following conditions are possible "Alternative Causes" of EVH in a patient with or without HCV: Mallory-Weiss tear; arteriovenous malformation; peptic ulcer disease; gastritis; esophagitis; carcinoma of the upper gastrointestinal tract; portal hypertensive gastropathy with any causes other than HCV as the Primary Cause; gastric antral vascular ectasia syndrome ("GAVE" syndrome, or "watermelon stomach" syndrome), or any other non-variceal source of upper gastrointestinal hemorrhage; exposure to or ingestion of hepatotoxin; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

separately or in a synergistic fashion with HCV, the progression of liver damage).

(D) **Hepatocellular Carcinoma.** **Hepatocellular Carcinoma** ("HCC") is a malignant tumor arising in the liver made up of cells with a distinct hepatic source. Proof of this condition shall require histologic confirmation by transcutaneous core biopsy or open wedge biopsy which demonstrates the presence of canaliculi between tumor cells by electron microscopy. This biopsy may be done *in vivo*, in post-mortem examination or after explanation. The following conditions are possible "Alternative Causes" of HCC in a patient with or without HCV: metastasis from an extra-hepatobiliary source; exposure to or ingestion of hepatotoxins; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

(E) **Portal Systemic Encephalopathy.** **Portal Systemic Encephalopathy** ("PSE") is a brain syndrome due to liver disease. Proof of this condition shall require all of the following:

- (i) An electroencephalogram exhibiting slowing of the redominant frequency of brain waves to 4 cps or lower;
- (ii) Arterial blood ammonia levels performed in a CDC-certified laboratory that are above the high normal reference range published by the laboratory doing the assay on at least one occasion within 30 days of the electroencephalogram;
- (iii) A CT or MRI of the head which reveals no abnormality or variation from normal; and
- (iv) One or more of the following clinical features, in the absence of evidence of organic or psychiatric disorder: disturbed consciousness, personality changes, intellectual deterioration, or slow speech.

The following conditions are possible "Alternative Causes" of PSE in a patient with or without HCV: administration to the Recipient, by any route, of any medication with hypnotic, sedative, ataractic or analgesic properties within 24 hours of the qualifying EEG examination; a history of head trauma within a 30-day period prior to the qualifying EEG examination; acute alcohol intoxication with serum ethanol in excess of 100 mg/liter within 24 hours of the qualifying EEG examination; acute or chronic retention of carbon dioxide with a partial pressure of carbon dioxide in peripheral arterial blood which is in excess of 50 mm Hg within 48 hours of the qualifying EEG examination; fulminant hepatic failure; other vascular causes, such as stroke or infections related to immune deficiency; exposure to or ingestion of hepatotoxins; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

(F) **Renal Failure.** **Renal Failure** is progressive renal insufficiency. Proof of this condition shall require both of the following:

- (i) Renal biopsy within the last six months showing changes consistent with and diagnosed as membranoproliferative glomerulonephritis; and
- (ii) Chronic dialysis performed at least once a week over a period longer than ninety days immediately preceding the designation of Renal Failure.

The following conditions are possible "Alternative Causes" of Renal Failure in a patient with or without HCV: the presence on kidney biopsy of findings compatible with acute tubular necrosis or toxic injury; a history of prolonged hypotension (systolic blood pressure <70 mm Hg for >15 min) within thirty days of the onset of dialysis; a history of intravenous administration of >50 ml of iodinated contrast medium within thirty days of the onset of dialysis; pre-renal azotemia; drug nephrotoxicity; exposure to or ingestion of hepatotoxins; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

(G) **Spontaneous Bacterial Peritonitis.** **Spontaneous Bacterial Peritonitis** ("SBP") is bacterial infection of ascitic fluid in the absence of perforation of any intra-abdominal organs, abscess, infection of any intra-abdominal organ or structure, or any infectious process in the body which might have contaminated an otherwise sterile collection of ascitic fluid. Proof of this condition shall require all of the following:

- (i) paracentesis fluid analysis with all of the following tests and all of the following results:

TEST	RESULT
Polymorphonuclear (PMN) cell count	PMN >250/mm <sup>3</sup>
Bacterial culture at Bedside with blood Culture bottles for aerobic And anaerobic organisms	Positive Growth (But not if three or more organisms or any anaerobic organisms are found)
Gram Stain	Absence of multiple organisms

- (ii) an abdominal series of x-rays that fails to identify any evidence of perforation of an intra-abdominal organ; and
- (iii) abdominal ultrasound with doppler and color flow mapping or Magnetic Resonance Imaging with angiography (MRI) of the portal and hepatic veins and of the inferior vena cava which demonstrates their patency.

The following conditions are possible "Alternative Causes" of SBP in a patient with or without HCV: exposure to or ingestion of hepatotoxin; or consumption of significant amounts of alcohol (consumption of enough alcohol for a sufficient period of time to produce, either separately or in a synergistic fashion with HCV, the progression of liver damage).

## ATTACHMENT B

### CHALLENGE PROCEDURES

#### Baxter's Challenges to Claims for Basic Payments

(1) **Dispute Resolution Concerning Exposure Only Payments.** In the event that Baxter decides to challenge a claim for an Exposure Only Payment, Baxter shall submit a Notice of Challenge to the Settlement Administrator, Class Counsel, and the settlement class member (and any identified individual counsel for the class member) no later than 60 days after final approval of the settlement. The Notice of Challenge shall state the reasons for the challenge and shall include any evidence relied upon in support of the challenge. The settlement class member and Class Counsel have the right to submit a written response to Baxter's Notice of Challenge, including any supplemental or rebuttal evidence, to Baxter and to the Special Master (who will decide the challenge) within 30 days of the date of the Notice of Challenge. It is the settlement class member's burden to prove that the Recipient was infused with Gammagard® IVIG during the Window Period. Baxter shall then have 15 days within which to either withdraw its challenge or file a reply. The Special Master shall issue an Order deciding the challenge based solely on the written submissions of each side, without any discovery, oral testimony or oral argument by either side. The Special Master shall provide copies of the Order to the settlement class member, Baxter, Class Counsel, and the Settlement Administrator.

(2) **Dispute Resolution Concerning Past Infection and Current Infection Payments.** In the event that Baxter decides to challenge a claim for either a Past Infection or Current Infection Payment, Baxter shall submit a Notice of Challenge to the Settlement Administrator, Class Counsel, and the settlement class member (and any identified individual counsel for the class member) no later than 60 days after receiving from the Settlement Administrator the completed Supplemental Medical Information Form submitted by the class member. The Notice of Challenge shall state the reasons for the challenge and shall include any evidence relied upon in support of the challenge. Baxter may file a Notice of Challenge on either (or both) of the following grounds: (a) the settlement class member submitting the claim has failed to supply the information and documents required and/or (b) there is evidence of "Alternative Causation." "Alternative Causation" means the Recipient's medical records reveal exposure to credible alternative risk factors for HCV, including, but not limited to, unscreened blood transfusions; infusions or transfusions of therapies and materials derived from whole blood, such as plasma, platelets, packed red blood cells, and other IVIGs; needle sticks; and illegal drug use, prior to the Recipient's diagnosis with HCV; OR any of the following objective indications in the Recipient's medical records suggesting that HCV infection or liver disease occurred prior to the Recipient's receipt of Gammagard® IVIG or January 1, 1993, whichever date is later: (i) elevated results in liver function tests; (ii) positive test results in antibody or antigen tests for the presence of HCV; (iii) biopsy results showing the presence of or consistent with HCV; (iv) hepatomegaly by physical examination or sonograms; (v) liver transplant; (vi) diagnosis of cirrhosis; or (vii) medical diagnosis by treating doctors referring to chronic or active liver disease. Mere evidence of Alternative Causation shall not be sufficient to defeat a claim; instead, Baxter shall have the burden of proving that Alternative Causation was a more likely cause of the Recipient's HCV infection than the Recipient's infusion with Gammagard® IVIG.

Baxter has the right to submit a request for further information to the settlement class member by attaching such request to Baxter's Notice of Challenge. Any objection by the class member to the request for information shall be submitted to the Special Master, with a copy to Baxter, within 15 days of the Notice of Challenge. In the absence of such an objection, the class member shall produce the requested information to both Baxter and the Special Master within 30 days of the date of the request. If an objection is made to the request for further information, Baxter shall have 15 days in which to respond to the objection and the Special Master shall rule on the objection. If the Special Master approves the information request in whole or in part, the class member shall produce the information to both Baxter and the Special Master within 30 days after the date of such approval. Upon the production of such further information, Baxter shall have 15 days in which to withdraw its Notice of Challenge or to supplement its Notice of Challenge. If the challenge is not withdrawn, the class member and Class Counsel have the right to submit a written response, including any supplemental or rebuttal evidence, to Baxter and to the Special Master within 45 days of the production of the further information.

In the event that no further information is sought by Baxter, the settlement class member and Class Counsel have the right to submit a written response, including any supplemental or rebuttal evidence, to Baxter and to the Special Master within 30 days of the date of the Notice of Challenge. Similarly, if upon the class member's objection to Baxter's request for further information, the Special Master determines that no further information need be produced, the class member and Class Counsel have the right to submit a written response, including any supplemental or rebuttal evidence, to Baxter and to the Special Master within 30 days of the ruling on the request for further information. In connection with any such written response, the class member shall have the burden of submitting the information required by the Supplemental Medical Information Form and proving that the Recipient identified in the claim was infused with Gammagard® IVIG during the Window Period and that such infusion caused the Recipient's HCV infection.

Once the deadlines for all written submissions has passed, the Special Master shall promptly review the matter and, generally, will issue an Order resolving the challenge based solely on the written submissions of the parties, providing copies of the Order to the settlement class member, Baxter, Class Counsel and the Settlement Administrator. However, the Special Master shall have the discretion to request clarification or additional information from either party. Any such request by the Special Master shall be communicated to both sides, and both sides shall have the right to respond to any such request. The Special Master shall have the discretion to conduct a hearing on the Special Master's own volition or at the request of Baxter, the class member or Class Counsel. In the event that the Special Master concludes that such a hearing would be appropriate, the Special Master shall attempt to schedule the hearing within 60 days after the dispute has been submitted to the Special Master for resolution. The hearing shall be conducted at a

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

location convenient for the parties, taking into account the residence of the class member and any appropriate witnesses. Alternatively, the hearing may be conducted telephonically. Following the hearing, the Special Master shall promptly issue an Order resolving the challenge, providing copies of the Order to the class member, Baxter, Class Counsel, Settlement Administrator and the Court.

(3) **Objections to the Special Master's Orders.** Any Order that would result in the denial of an Exposure Only Payment will be reviewed by the Court with or without objection. Any other Order of the Special Master as to which objections are not timely filed shall become final with respect to the issues resolved by the special master. Any party dissatisfied with any Order of the Special Master shall have 30 days after the issuance of the Order to file objections to the Order with the Court, addressed to the Honorable Manuel L. Real, United States District Judge, United States District Court, Central District of California, 312 North Spring Street, Los Angeles, California 90012-4793. Where objections are timely filed and served on all other parties, the other parties shall have 30 days within which to file any response, followed by 15 days for the objecting party to file a reply. Thereafter, the Court shall approve, modify or reject the Order of the Special Master or request that the Special Master reconsider the objection and issue a new Order.

### **Baxter's Challenges to Applications for Additional Payments**

(1) **Baxter's Right to Seek Additional Information Relating to Additional Payments.** Within 90 days of the date Baxter receives an application for an Additional Payment with all required supporting documents, Baxter shall determine whether the information submitted justifies the requested Additional Payment. If Baxter deems the information submitted inadequate, Baxter may: (1) request additional medical documentation or responses to written questions; (2) submit the application and medical records to a physician of its choosing; (3) conduct an interview of the Recipient and/or settlement class member; and/or (4) require the Recipient to submit to a medical examination by a physician of Baxter's choosing.

Where Baxter elects to submit the application to a physician of its choosing, Baxter shall arrange to receive the written opinion of such physician within 150 days after receipt of the claim documents, or within 60 days after receiving any supplemental information requested by Baxter pursuant to the preceding paragraph, whichever is later. If the physician concurs in the diagnosis and eligibility under the settlement, then the Additional Payment shall be made. If the physician chosen by Baxter does not agree with the diagnosis or with eligibility, Baxter shall elect within 30 days after it receives the report from the physician selected by Baxter either to make the Additional Payment or to challenge the application.

(2) **Dispute Resolution for Additional Payments.** If Baxter elects to challenge the application for an Additional Payment, Baxter shall provide written notice to the class member and to the attorney, if any, for such class member. Baxter's challenge shall be submitted for binding arbitration to a three-person committee of health care professionals as follows:

(a) **Selection of Panel.** The settlement class member shall select one panelist with credentials and qualifications described in Section (e)(i) below and shall send written notification to Baxter of the selection. Within 20 days of receipt of said notification, Baxter shall select one additional panelist with credentials and qualifications described in Section (e)(i) and send written notification to the class member of the selection. The class member and Baxter shall then jointly notify the two panelists of their nomination and shall request those two panelists to disclose any conflicts of interest or other reasons that would prevent service on the panel. If the disclosures require no disqualification, the two panelists shall be instructed to select by mutual agreement a third panelist from the panel listed in Section (e)(ii) below. If the disclosures require the disqualification of a panelist nominated by the parties, the party that nominated the panelist shall select, within ten days of the disqualification, a new panelist with credentials and qualifications described in Section (e)(i), after which the newly selected panelist shall participate, along with the other original panelist, in the selection of the third panelist. If, but only if, none of the persons listed in Section (e)(ii) are willing or able to serve on the panel in a timely fashion, the two panelists shall jointly select a third panelist with credentials equal or similar to those of the individuals listed in Section (e)(ii), keeping in mind the desire to have arbitration decisions rendered by well-recognized professionals experienced in the research, treatment or education about HCV. After the third panelist has been selected by the two panelists nominated by the parties, the third panelist shall disclose any conflicts of interest or other reasons that would prevent service on the panel. If the disclosures require no disqualification, the panel shall be confirmed and the arbitration shall proceed. If the disclosures require the disqualification of the panelist nominated by the other panelists, the two panelists shall be instructed to select a new panelist from the persons listed in Section (e)(ii). In the event that any party fails to make a nomination within the required deadline, the other party may obtain judicial relief compelling the first party to make the required nomination.

(b) **Arbitration Schedule.** The arbitration proceeding shall be conducted as soon as possible and no later than 120 days from the date that Baxter demands arbitration. The parties shall request the panel to render a decision within 30 days after all evidence is submitted. The parties may, by mutual agreement, extend any of the deadlines. The panel of medical professionals may likewise, for good cause shown, extend or advance any of those deadlines.

(c) **Effect of Decision.** The decision of the panel may be entered as a judgment of the court, and may be challenged solely on the grounds specified in Sections 10 and 11 of the Federal Arbitration Act (9 U.S.C. §§ 10-11). If the decision of the panel is in favor of the settlement class member, then the specified payment shall be made within 30 days of the award. Such payment shall include interest at the rate of 6% per annum simple interest from 150 days after the submission of the Additional

**(d) Payment of Fees and Costs of Panel.** The fees and costs of the panel shall be paid by Baxter except as follows. If Baxter believes that the application is either frivolous or presented without a good faith belief that the Recipient qualifies for the Additional Payment(s), Baxter shall have the option of notifying the settlement class member at least 30 days prior to the hearing of Baxter's intention to seek an order from the panel directing the class member to pay the fees and costs of the panel if the application is denied. If such notice is given by Baxter and the panel ultimately not only denies the application but also finds that the application was either frivolous or presented without a good faith belief that the Recipient qualifies for the Additional Payment(s), the panel shall order the class member to pay all of the fees and costs of the panel (reimbursing Baxter for any amounts previously advanced by Baxter). Notwithstanding the foregoing provision, each party shall be responsible for his or her own attorney's fees and costs in connection with the arbitration.

**(e) Qualifications of Panel.**

**(i) Panelists Selected by the Parties.** Each party shall nominate as an arbitrator an individual who has been appointed to an academic position in a United States (AAMC) approved medical school, either as a full-time, part-time or volunteer appointment, in a department or division with a specialty designation relating directly to gastroenterology or to infectious disease. No such panelist may serve more than twice as a panelist in arbitrations under this settlement or any comparable settlements involving other individuals and Baxter.

**(ii) Selection of the Third Panelist.** The arbitrators selected by the parties shall select a third panel member from the following list of individuals:

Professor of Medicine  
Harvard Medical School &  
Chair, Dept. of Gastrointestinal Diseases  
Brigham & Women's Hospital  
Boston, MA

Professor & Chair  
Dept. of Epidemiology  
School of Public Health  
Columbia University  
New York, NY

Professor & Chair  
Dept. of Gastroenterology  
Duke University Medical School  
Durham, NC

Professor & Chair  
Dept. of Epidemiology  
School of Hygiene & Public Health  
Johns Hopkins University  
Baltimore, MD

Professor & Chair  
Dept. of Gastroenterology  
Pritzker School of Medicine  
University of Chicago  
Chicago, IL

**ATTACHMENT C**

CLAIM NO.: (To be completed by Settlement Administrator)
---

**GAMMAGARD® INTRAVENOUS IMMUNE GLOBULIN**  
**CLASS ACTION SETTLEMENT RELEASE**

***If you have questions about this Release, consult with your attorney. If you do not have an attorney, contact Class Counsel. You must sign this Release and return it to the Settlement Administrator before your claim can be paid.***

\_\_\_\_\_  
Class Member's Last Name

\_\_\_\_\_  
First Name

\_\_\_\_\_  
Social Security Number

I am a participant in the Class Action Settlement Agreement Re Gammagard® Intravenous Immune Globulin Claims ("Agreement") approved by the United States District Court for the Central District of California.

In return for receiving payment or payments under that Agreement, I release and discharge BAXTER HEALTHCARE CORPORATION and BAXTER INTERNATIONAL INC. ("Baxter"), and all of its present and former corporate parents, subsidiaries, affiliates, divisions, partners and joint venturers, as well as all suppliers, distributors, pharmacies, medical providers and any other person or entity, and all shareholders, directors, officers, employees, agents, servants, persons, insurers, reinsurers and counsel of each of the foregoing, as well as their predecessors and successors, from any and all claims I may have now or in the future relating in any way to alleged exposure to and/or infection with hepatitis C arising out of the infusion, administration, receipt or use of or contact with Gammagard® IVIG during the period from January 1, 1993 to February 24, 1994.

I understand that this Release does not extinguish rights I might have to Additional Payments under the Agreement, but does extinguish all other claims, lawsuits, causes of action and demands for losses and damages of every kind, including but not limited to, damages for personal injuries, death, mental or physical pain or suffering, loss of income, earnings and earning capacity, doctor bills, hospital bills, nursing costs, drug or pharm aceutical costs, medical monitoring, loss of consortium, companionship, society or affection, damage to familial relations, loss of enjoyment of life, economic, business or contractual losses, punitive or exemplary damages, statutory damages, interest, costs, attorneys' fees, or any other compensation or relief whatsoever, whether known or unknown, foreseen or unforeseen, suspected or unsuspected, whether in law or in equity, or before administrative agencies or departments, that I ever had, now have, or hereafter can, shall or may have, relating in any way to alleged exposure to and/or infection with hepatitis C arising out of the infusion, administration, receipt or use of or contact with Gammagard® IVIG during the period from January 1, 1993 to February 24, 1994.

I understand that this Release is intended to discharge and extinguish not only those claims which I have or may have against Baxter but also those claims that could be brought by others, including my spouse, children, heirs, estate, beneficiaries, successors, subrogees, assigns, executors, attorneys, agents or any other legal representatives, including but not limited to wrongful death and survival actions.

I agree to cooperate fully and to execute any and all required documents and to take any additional actions that may be necessary or appropriate to give full force and effect to the terms and intent of this Release.

I represent and warrant that I have not sold, transferred, conveyed, assigned or hypothecated any rights, either collectively or individually, in whole or in part, in any of the matters released herein.

I agree to assume exclusive responsibility for the payment of any lien or liens, past, present or future, known or unknown, by any person, entity, business, firm, corporation or government entity or agency relating in any way to alleged exposure to and/or infection with hepatitis C arising out of the infusion, administration, receipt or use of or contact with Gammagard® IVIG during the period from January 1, 1993 to February 24, 1994, including but not limited to medical expenses paid for or reimbursed by private health insurers, Medicare, Medicaid, or any other public health insurers.

I agree that if the Agreement is changed or vacated in any way, this Release will remain in full force and effect so long as I receive all of the same payment or payments for which I am eligible under the Agreement.

I agree that this Release shall be governed, construed and interpreted in accordance with the laws of the State of Illinois.

I understand and agree to the terms of this Release. I had an opportunity to consult attorneys of my own choice to solicit advice with respect to my rights and the meaning and effects of this Release and, if I did not consult an attorney, I knowingly and voluntarily elected not to do so.

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**

I have full power and authority to make, execute and deliver this Release and am under no legal disability material to my ability to execute this Release. I have carefully read this Release, signed it as my own free act, and intend to be legally bound thereby.

I declare under penalty of perjury that all the statements above are true and correct.

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Signature of Class Member  
(or Authorized Guardian or Representative)

**When signed please mail to the SETTLEMENT ADMINISTRATOR at:**

**Gammagard® IVIG Class Action Settlement Administrator  
P.O. Box 131620  
Dallas, TX 75313**

**ANY QUESTIONS? PLEASE CALL 1-888-921-4776**